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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,674	12/04/2000	Kenneth Jacobs	1290.1018-008	8269

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EXAMINER
MITRA, RITA

ART UNIT	PAPER NUMBER
1653	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No. 09/729,674	Applicant(s) JACOBS ET AL.	
	Examiner Rita Mitra	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *6 and 9-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 December 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 7, 8, drawn to an isolated polynucleotide comprising or related to SEQ ID NO: 1, vector, host cell and a process for producing a protein recombinantly, classified in class 435, subclass 69.1.

II. Claims 6, 9-12, drawn to an isolated protein comprising or related to SEQ ID NO: 2, a composition comprising the protein related to SEQ ID NO: 2 classified in class 530, subclass 350, class 514, subclass 2

III. Claim 13, drawn to an isolated polynucleotide comprising or related to SEQ ID NO: 19, classified in class 536, subclass 23.1.

IV. Claim 14, drawn to an isolated protein comprising or related to SEQ ID NO: 20, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

The DNA of groups I and III are unrelated. They differ with respect to their structures and physicochemical properties. The polynucleotides have separate and distinct sequences and encode unrelated proteins. Therefore, the inventions are distinct.

The proteins of groups II and IV are unrelated. The polypeptides have separate and distinct sequences encoding unrelated proteins. Therefore, the inventions are distinct.

The DNA of groups I and III is related to the protein of groups II and IV by virtue of the fact that the DNA codes for the protein, respectively. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, the inventions are distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Attorney Lawrence Perry on June 6, 2002 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-5, 7 and 8. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6, 9-14 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, claims 1-5, 7 and 8 are currently pending and are under examination.

Priority

It is noted that applicant has cited one or more applications as priority documents under 35 U.S.C. 119(e) and 120. Applicant is requested to update the status of the documents to reflect their current status. The parent application 09/197, 886 fails to provide the support to clone bd306_7 and SEQ ID NO: 1 and SEQ ID NO: 2. Therefore, Application 09/539330 filed on March 30, 2000 is considered for the priority date applied in the present application.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"

Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 101 because the specification does not provide either a specific or substantial asserted utility or a well-established utility, and thus, does not support the claimed invention. The claimed polynucleotides are not supported by either a specific asserted utility or a well established utility because the specification fails to assert any utility for the claimed polynucleotides or the encoded proteins and neither the specification as filed nor any art of record disclose or suggest any activity for the claimed polynucleotides or the encoded proteins such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed.

The specification, on pages 3-6 and 311-312 describes clone bd306_7 to which the instant invention relates. Applicants assert (page 312) that based on various alignments with database submissions; the claimed polynucleotides may encode polypeptides that share some activity with T21281 (Human gene signature), U47621 (Human nucleolar autoantigen No55), X97607 (G. gallus cartilage associated protein), R95913 (Neural thread protein) for example.

The alignments have not been provided and no percent similarity is disclosed. Furthermore, Applicants indicate at page 312 that two regions of bd306_7 roughly 148-189 and 298-367 are similar to each other and one copy of this region is found in cartilage associated protein, but both are present in No55. However, the specification fails to provide any activity of these two regions (148-189 and 298-367) or the full length polypeptide which would be similar to the activity of a cartilage associated protein or a nuclear autoantigen protein No55. Further this assertion does not address to the similarity to submissions T21281 (Human gene signature), R95913 (Neural thread protein).

Based on the specification (pages 3-6 and 311-312), no biological activity has been set forth for the polypeptide encoded by polynucleotide of clone bd306_7 nor any use for the polynucleotide itself has been provided. However, speculative biological activities have been provided on pages 423-441 of the specification. For example, the use of the polynucleotide for further research is described here (page 423). This use is not an acceptable patentable utility because one skilled in the art should not have to discover for themselves the use of the claimed polynucleotides. This situation requires carrying out future research to identify or reasonably confirm a "real world" context of use and therefore do not define specific and substantial utility.

The specification on page 424 states that the polynucleotide and proteins can be used as a nutritional source or supplements. This use is considered to be a " throw away" utility and does not distinguish the claimed polynucleotide over any other polunucleotide. The utility is not specific or substantial.

Other activities that the protein encoded by the polynucleotide may exhibit are listed throughout pages 423-441 of the specification. However, these activities are purely speculative. In summary, the polynucleotides claimed do not have a credible, specific or well-established utility and therefore lacks utility under 35 U.S.C. 101.

Claim 1 (i, j), are drawn to a polynucleotide encoding a protein comprising a fragment of SEQ ID 2. The specification does not describe the functional properties of these protein fragments, and the structural information is limited. While the specification enumerates several

known assays for biological activity (pp. 423-441), it does not guide the selection of a specific assay that would be used to screen the biological activities of the claimed fragments.

Claim 1 (e, f) is drawn to polynucleotides encoding full-length proteins of clone bd306_7. It is not clear from the description of the clone (specification pages 3-6, 311-312) about the protein structure, aside from its full-length amino acid sequence, and/or its function.

Claim 1 (a-d, j) are directed to polynucleotides comprising the sequence of SEQ ID NO: 1 and fragments thereof. As discussed above, based on the specification (pages 3-6 and 311-312) it is unclear what activity the claimed polynucleotides possess, what activity the encoded proteins or protein fragments possess and therefore unclear how a person having skill in the art might use the claimed polynucleotides. It would require undue experimentation for a person having skill in the art to be able to use the claimed polynucleotides. It is *a priori* unpredictable based on the instant disclosure what activity the claimed polynucleotides possess because no correlation has been made between the claimed polynucleotides and a specific activity.

In the instant case, the failure of applicants to specifically identify why the claimed invention is believed to be useful renders the claimed invention deficient under 35 USC 101. No specific biological activity has been identified for the protein set forth in SEQ ID NO: 2 or for the polynucleotides of SEQ ID NO: 1 encoding the protein other than the fact that the protein may be secreted (p. 311). The person having ordinary skill in the art would not be able to identify any specific activity for the protein comprising or related to SEQ ID NO: 2 based on its structure alone for the reasons set forth above. General statements that a composition has an unspecified biological activity or that do not explain why a composition with that activity is believed to be useful fails to set forth a "specific utility." Brenner v. Manson, 383 US 519, 148 USPQ 689 (Sup. Ct.1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful is insufficient under 35 USC 101).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7 and 8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial or well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

"The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear from the claim or the specification how in claim 1 (j), that the polynucleotide that must hybridize to the polynucleotide of items (a-i) of claim 1 encode the same protein. In one instance, the polynucleotide is the coding strand and in the other it is the antisense strand. If the sense strand contains 5' ATG (encodes Met), the antisense strand is 5' CAT (encodes His).

Additionally, in claim 5 it is unclear as to whether or not the process claimed would have resulted in a protein that has the same physical, chemical, and biological properties and functions as the polynucleotide which is SEQ ID NO: 1 or the cDNA insert of ATCC 98264 since the present application neither indicates a function for the polynucleotide nor the protein encoded by the claimed polynucleotides.

Claims 7 and 8 recite the limitation "protein" in the first line of each claim. There is insufficient antecedent basis for this limitation in the claims, since these claims are dependent on a non-elected claim.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 5, 7 and 8 are rejected under 35 USC 102 (a) as being anticipated by Agostino et al. (August 9, 1999). Agostino et al. (AAX60801) teach a cDNA clone bd306_7, codes for a human secreted protein (AAY17219) from human fetal and adult organ cDNA library, wherein the secreted protein nucleic acid sequences correspond to clone bd306_7 having 100% nucleic acid sequence identity to SEQ ID NO: 1, (see alignment result, Database: N_Geneseq_032802, Accession NO: AAX60801) and 99.9% amino acid sequence identity to SEQ ID NO: 2, (see alignment result, Database: A_Geneseq_032802, Accession NO: AAY17219). Agostino's cDNA insert length is 3871 bp, that encodes a protein having 401 amino acids of SEQ ID NO: 2, therefore this sequence is considered for hybridizing to the polynucleotide of claim 1 and 7. Agostino's clone bd306_7 is deposited in composite clone ATCC 98599 (claim 8), thus Agostino et al. anticipate claims 1-3, 5, 7 and 8 of the instant application.

Claims 1-5, 7 and 8 are rejected under 35 USC 102 (a) as being anticipated by Jacobs et al. (WO 99/26961; June 3, 1999). Jacobs et al. ('961) teach a polynucleotide as set forth in SEQ ID NO: 1 encoding human secreted protein as set forth in SEQ ID NO: 2 (claim 1). The cDNA clone bd306_7 of Jacob is deposited in composite clone ATCC 98599 (see summary and claim 1 and page 48, of '961), thus anticipating claims 7 and 8 of instant application. Jacobs' cDNA is

inserted in vector pED6 and pNOTs (see page 48) and expressed in bacterial host cells (see page 50) and mammalian host cells (see page 51 and 57) thus anticipating claims 2-5 of instant application. Jacobs' polynucleotide sequence is considered for hybridizing to the polynucleotide of SEQ ID NO: 1 of claim 1 (a-j); and polypeptide sequence is considered for a protein of SEQ ID NO: 2; and thus anticipates claim 1 of instant application.

Conclusions

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 p.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

Rita Mitra

Rita Mitra, Ph.D.
June 12, 2002